2018 Current Fiscal Year Report: Recombinant DNA Advisory Committee

Report Run Date: 06/05/2019 12:43:28 PM

1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2018

3. Committee or Subcommittee	3b. GSA Committee No.
Recombinant DNA Advisory Committee	1013

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	06/30/2017	06/30/2019	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
42 USC 282(b)(16)	11/04/1988	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports No Reports for this FiscalYear

17a. Open 0 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 0

Meetings and Dates

No Meetings

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$0.00	$15,000.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$129,705.00	$132,170.00
18a(4). Personnel Pmts to Non-Member Consultants	$0.00	$0.00
18b(1). Travel and Per Diem to Non-Federal Members	$0.00	$94,875.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$0.00	$0.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	$0.00	$73,353.00
18d. Total	$129,705.00	$315,398.00
19. Federal Staff Support Years (FTE)	0.80	0.80

20a. How does the Committee accomplish its purpose?

The Recombinant DNA Advisory Committee (RAC) was established in 1974 in response to public concerns regarding safety of manipulating genetic material through the use of recombinant DNA techniques, which was the emerging biotechnology of that time. The RAC is a federal advisory committee whose current purpose is to advise the NIH on the application and oversight of research involving recombinant or synthetic nucleic acid molecules. This may include the review of human gene transfer trials, advances in recombinant or synthetic nucleic acid technology, and the ethical and safety considerations associated with novel research in this area or forms of such research that may pose unique risks. The RAC also helps the NIH conceptualize and organize safety symposia and policy conferences on these matters when diverse perspectives and broad scientific and public participation are needed to explore an issue fully. The RAC is comprised of experts from a wide range of scientific and medical disciplines and also includes ethicists and patient and public representatives. In FY 18, the Committee did not meet, given it was a period of transition. NIH is restoring the RAC, which has long played a role in advising the NIH director on human gene transfer trials, to its original vision of focusing on the scientific, safety, and ethical issues associated with emerging biotechnologies.

20b. How does the Committee balance its membership?

Under its current charter, the committee may consist of up to 21 voting members, including the Chair, appointed by the Director, NIH. A majority of the voting members are knowledgeable in relevant scientific fields, e.g., molecular genetics, molecular biology, recombinant DNA or synthetic nucleic acid research, including clinical gene transfer research. Of the 21 members, at least four members of the Committee must be knowledgeable in fields such as public health, laboratory safety, occupational health, protection of human subjects of research, the environment, ethics, law, public attitudes or related fields. In addition, there may be non-voting representatives from other Federal agencies.

20c. How frequent and relevant are the Committee Meetings?

The Committee has typically met as many as 4 times per year to address and consider the current state of knowledge and technology regarding recombinant or synthetic nucleic acid research. The issues are of interest to a broad range of individuals and organizations, including researchers, the biotechnology industry, other Federal agencies, research participants, and other members of the public. In addition to the Committee meetings, policy conferences and safety symposia are held to discuss emerging issues surrounding recombinant or synthetic nucleic acid research. In FY 18, the Committee did not meet, as NIH assessed that no protocols met the requirements for RAC review. The

NIH is proposing that, moving forward, the RAC meet as needed to provide advice to NIH and to serve as a public forum for scientific, safety, and ethical issues associated with emerging biotechnologies.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

This Committee is composed of recognized experts in the field of biotechnology research as well as non-scientists who are nationally known experts in fields such as law, ethics, and standards of professional conduct and practice. The composition of the RAC, which may evolve based on the proposed revisions to the role of the committee, provides a unique balance of expertise and opinions that cannot be obtained from federal staff or on an ad hoc basis because of the diversity in scientific and non-scientific viewpoints needed, the importance of non-federal perspectives, and the need for continuity as the Committee considers issues over time.

20e. Why is it necessary to close and/or partially closed committee meetings?

N/A

21. Remarks

Reports: This committee did not produce any public reports. Meetings: In FY18, there were no meetings held as NIH assessed that no protocols met the requirements for RAC review. Costs: The decrease in operating costs for FY18 were due to no meetings being held during the FY. The decrease in Federal Staff costs were due to incorrectly reported salaries in the FY17 ACR. Members: The term for Richard Whitley changed due to a reappointment. As such, his term of service end date is different than what was reported on the FY17 ACR. The DFO and Committee Decision Maker positions are held by the same individual because of the assignment of responsibilities within the Institute.

Designated Federal Officer

Marina O'Reilly Director, Recombinant DNA Activities Program, Division of Biosafety, Biosecurity, and Emerging Biotechnologies Policy, Office of Science Policy

Committee Members	Start	End	Occupation	Member Designation
ADELMAN, ZACH	11/28/2016	07/31/2020	ASSOCIATE PROFESSOR	Special Government Employee (SGE) Member
ALBRITTON, LORRAINE	10/30/2016	07/31/2020	PROFESSOR	Special Government Employee (SGE) Member
ATKINS, MICHAEL	11/26/2013	01/31/2018	DEPUTY DIRECTOR	Special Government Employee (SGE) Member
BORIS-LAWRIE, KATHLEEN	10/01/2017	07/31/2020	PROFESSOR OF MICROBIOLOGY	Special Government Employee (SGE) Member
CHO, MILDRED	02/03/2016	07/31/2019	PROFESSOR	Special Government Employee (SGE) Member
CURRY, WILLIAM	04/22/2014	01/31/2018	DIRECTOR	Special Government Employee (SGE) Member

DIGIUSTO, DAVID	09/05/2017	07/31/2019	EXECUTIVE DIRECTOR	Special Government Employee (SGE) Member
DONAHUE, J.	04/19/2015	07/31/2018	PROFESSOR OF MEDICINE	Special Government Employee (SGE) Member
HEARING, PATRICK	01/25/2015	07/31/2018	PROFESSOR	Special Government Employee (SGE) Member
KAUFMAN, HOWARD	01/15/2016	07/31/2018	CHIEF SURGICAL OFFICER	Special Government Employee (SGE) Member
LEE, BENHUR	12/11/2016	07/31/2020	PROFESSOR	Special Government Employee (SGE) Member
LEE, DEAN	08/30/2016	07/31/2019	ASSOCIATE PROFESSOR	Special Government Employee (SGE) Member
MCCARTY, DOUGLAS	03/07/2016	07/31/2019	ASSOCIATE PROFESSOR	Special Government Employee (SGE) Member
PORTEUS, MATTHEW	10/01/2017	07/31/2020	ASSOCIATE PROFESSOR OF PEDIATRICS	Special Government Employee (SGE) Member
ROSS, LAINIE	04/19/2015	07/31/2018	CAROLYN AND MATTHEW BUCKSBAUM PROFESSOR OF CLINICAL ETHICS	Special Government Employee (SGE) Member
WALDEN HARDISON, ANGELICA	09/10/2013	01/31/2018	COMPLIANCE ANALYST	Special Government Employee (SGE) Member
WHITLEY, RICHARD	11/26/2013	01/31/2019	DISTINGUISHED PROFESSOR OF PEDIATRICS	Special Government Employee (SGE) Member

Number of Committee Members Listed: 17

Narrative Description

The mission of the Recombinant DNA Advisory Committee (RAC) is to advise the NIH Director on the scientific, safety, and ethical dimensions of recombinant or synthetic nucleic acid research, including both basic laboratory and clinical research. The RAC conducts all of its meetings in public and webcasts the proceedings in order to inform researchers and the public. Historically, the mission of the RAC has been met through activities such as: 1) public review and discussion of exceptional human gene transfer protocols that raise significant new issues or concerns; 2) public review of certain experiments under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines); 3) public consideration of significant policy issues affecting the conduct of recombinant or synthetic nucleic acid research; 4) scientific workshops, safety symposia, or policy conferences and contributions to NIH Office of Science Policy (OSP) publications based on these workshops, etc. In an August 17, 2018, Federal Register Notice, NIH proposed that the RAC no longer review individual human gene transfer protocols. Rather, the committee will return to its original role serving as a public forum to advise NIH on scientific, safety, and ethical issues associated with emerging biotechnologies.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓

Trust in government	☑
Major policy changes	☑
Advance in scientific research	☑
Effective grant making	☐
Improved service delivery	☐
Increased customer satisfaction	☐
Implementation of laws or regulatory requirements	☐
Other	☐

Outcome Comments

NA

What are the cost savings associated with this committee?

	Checked if Applies
None	☐
Unable to Determine	☑
Under $100,000	☐
$100,000 - $500,000	☐
$500,001 - $1,000,000	☐
$1,000,001 - $5,000,000	☐
$5,000,001 - $10,000,000	☐
Over $10,000,000	☐
Cost Savings Other	☐

Cost Savings Comments

NIH supported basic and clinical research accomplishments often take many years to unfold into diagnostic tests and new ways to treat and prevent diseases.

What is the approximate Number of recommendations produced by this committee for the life of the committee?

848

Number of Recommendations Comments

In FY18, no recommendations were made because NIH determined no protocols met the criteria, defined by the NIH Guidelines, for RAC review. In an August 17, 2018, Federal Register Notice, NIH proposed that the RAC no longer review individual human gene transfer protocols. NIH is restoring the RAC to its original vision of advising NIH on scientific, safety, and ethical issues associated with emerging biotechnologies.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
0%

% of Recommendations Fully Implemented Comments
Due to the large breadth and complexity of the recommendations made by this committee that affect the broader biomedical research enterprise (both federally and privately funded research), NIH staff is unable to determine which recommendations have been fully or partially implemented solely in response to this committee's activities.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
0%

% of Recommendations Partially Implemented Comments
NA

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?
Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments
The agency provides meeting minutes, written reports, and oral presentations.

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	☑
Reallocated resources	☐
Issued new regulation	☐
Proposed legislation	☐
Approved grants or other payments	☐
Other	☑

Action Comments
The Committee has made recommendations to NIH on matters related to (1) the conduct and oversight of research involving recombinant or synthetic nucleic acid molecules, including the content and implementation of the NIH Guidelines, as amended, and (2) other NIH activities pertinent to recombinant or synthetic nucleic acid molecule

technology.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

NA

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	✓
Online Agency Web Site	✓
Online Committee Web Site	✓
Online GSA FACA Web Site	✓
Publications	
Other	

Access Comments

N/A